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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/809,236
Filing Date: March 25, 2004
Appellant(s): BASHIRI ET AL.

James M. Urzedowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/19/2009 appealing from the Office action mailed 1/29/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

Claims 16-19, 44, and 45 are under 35 USC 103 over Callol in view Globerman and Bashiri in further view of Ravenscroft (US 5,702,418).

The appeal brief repeated a typographical error made by the examiner in the final office action wherein Globerman was mistakenly referred to as "McGuinness". It is noted that claim 15 from which claims 16-19, 44, and 45 depend was correctly rejected over Callol in view of Globerman and Bashiri.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,585,757	**Callol**	**7-2003**
6,428,570	**Globerman**	**8-2002**
6,102,943	**McGuinness**	**8-2000**
6,165,178	**Bashiri et al.**	**12-2000**
6,699,280	**Camrud et al.**	**3-2004**
5,702,418	**Ravenscroft**	**12-1997**

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 20-24, 26-30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol (US 6,585,757) in view of Globerman (US 6,428,570). Callol discloses an expandable stent comprising a single stent backbone (18) extending from the proximal to the distal end of the stent and oriented in a direction which is substantially parallel to a longitudinal axis of the stent, the stent backbone being a single strut, and a plurality of interconnected stent members, the stent members consisting of first stent members and second stent members, the first stent members (16) being oriented in a substantially longitudinal direction in the unexpanded and expanded state, each of the second stent members (at least straight portion of 14) being oriented in a substantially longitudinal direction in the unexpanded state since a majority of this length is longitudinal.

Regarding the limitation of the stent members consisting of first and second stent members, the curved portion of (14) can be considered a bridge that is not one of the claimed plurality of interconnected stent members. In other words, the transitional phrase of "comprising" in line 3 of the claim allows for additional elements in the stent. The use of “consisting” for the stent members only limits what is considered the plurality of interconnected stent members to the first and second stent members. Alternatively, if about half of the curved portion of (14) along with an adjacent entire straight portion of (14) is considered a second member, then the second member can be considered substantially longitudinal in the unexpanded state since a greater length of the second member is longitudinally directed when in the unexpanded state. The stent backbone has greater column strength than the plurality of interconnected stent members because the backbone stretches the entire length of the stent. Although Callol discloses the second stent members (14) stretch open in the expanded configuration, it is not clear how circumferential the formerly longitudinally directed portions of (14) become in the expanded configuration.

Globerman discloses that it is well known in the art to fully expand a similarly wavy strut so that portions of the strut that are longitudinally directed when a stent is in its unexpanded state become circumferentially directed in the stent's expanded configuration (figures 14, 15). This allows the stent to have a greater radial expansion ratio and therefore the stent can treat a larger vessel while having a very small unexpanded profile. It would have been well within the purview of one skilled in the art to use second stent members (14) that expand in the manner taught by Globerman on the device of Callol so that it too would have this advantage. Regarding claim 20, although not expressly disclosed by Callol, therapeutic coatings on stents are well known in the art for increasing their biocompatibility and for treating surrounding tissue and such a coating would have been an obvious modification to one skilled in the art.

Regarding claims 21 and 22, see column 3, lines 47 of Callol.

Regarding claims 23 and 24, stent is made from wires.

Regarding claim 26, adjacent first and second stent members form closed loops.

Regarding claims 27 and 28, the second stent members (14) include a curved region and a straight region in the unexpanded configuration (figure 1 of Callol).

Regarding claim 30, the backbone is substantially straight.

Regarding claim 29, Callol does not disclose that the backbone comprises at least one substantially curved portion. However, Globerman discloses including a curved portion in a longitudinally directed stent segment (see figure 16). As is well known in the art, inclusion of a curved portion in an otherwise straight stent segment increases the flexibility of the stent. It would have been obvious to modify the device of Callol to include a curved portion in any of the straight, longitudinally directed stent members including the backbone in order to achieve greater flexibility.

Regarding claim 33, the backbone is radiopaque (column 3 lines 47-49).

Claims 1, 3, 20, 23, 24, 26-28, 30, 33, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuinness (US 6,102,943) in view of Globerman. McGuinness discloses an expandable stent comprising a single stent backbone (24 and 26 welded or adhered together; figures 1, 2a) which extends from the proximal to the distal end of the stent, the stent backbone being oriented in a direction substantially parallel to a longitudinal axis of the stent, the stent backbone being a single strut and a plurality of interconnected second stent members, each of the second stent members (straight portion of 28) being oriented in a substantially longitudinal direction in the unexpanded state. The stent backbone has greater column strength than the plurality of interconnected stent members because it is thicker than any of the other stent members. As discussed above in more detail regarding the limitation of a

plurality of interconnected stent members, the stent members consisting of first and second members, the curved portion (38) of members (28) can be considered a bridge that is not one of the claimed stent members. Alternatively, if a second stent member comprises straight portion (32) and half of a connected curved portion (34), it can be considered substantially longitudinally directed in the unexpanded configuration. Although McGuinness discloses the second stent members (28) stretch open in the expanded configuration, it is not clear how circumferential the formerly longitudinally directed portions of (28) become in the expanded configuration. McGuinness also fails to disclose first stent members that are longitudinally directed in the unexpanded and expanded state.

Globerman discloses that it is well known in the art to fully expand a similarly wavy strut so that portions of the strut that are longitudinally directed when a stent is in its unexpanded state become circumferentially directed in the stent's expanded configuration (figures 14, 15). This allows the stent to have a greater radial expansion ratio and therefore the stent can treat a larger vessel while having a very small unexpanded profile. It would have been well within the purview of one skilled in the art to use second stent members (14) that expand in the manner taught by Globerman on the device of McGuinness so that it too would have this advantage. Globerman also teaches including first stent members (35; figure 15) that are longitudinally directed in both the expanded and unexpanded stent and connect adjacent rings of the stent. These first stent members increase the structural integrity of the stent. It would have been obvious to add first stent members connecting the second stent members as taught by Globerman in order to increase the strength and structural integrity of the stent of McGuinness.

Regarding claim 3, see figure 3 of McGuinness

Regarding claim 20, although not expressly disclosed by McGuinness, therapeutic coatings on stents are well known in the art for increasing their biocompatibility and for treating

surrounding tissue and such a coating would have been an obvious modification to one skilled in the art.

Regarding claims 23 and 24, the backbone and first and second stent members are wires since they may be made from metal sheet and are therefore thin pieces of metal.

Regarding claims 27 and 28, the second stent members (14) include a curved region and a straight region in the unexpanded configuration (figure 1 of McGuinness).

Regarding claim 30, the backbone is substantially straight.

Regarding claim 33, the backbone is radiopaque when radiopaque adhesive is used to join 24 and 26 to form the backbone (column 6 lines 19-22 of McGuinness).

Regarding claim 40, the stent is constructed from a tube of stent material.

Claims 8-11,13-15, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol in view of Globerman as applied to claim 1 above, and further in view of Bashiri et al. (US 6,165,178). Callol in view of Globerman discloses the invention substantially as stated above but fails to disclose a push wire with its distal end being removably engaged to a proximal end of the stent, the first backbone extending from the distal end of the push wire. Callol discloses that the stent is balloon expandable and may be made of Nitinol. It would have been obvious to program the Nitinol stent for self-expansion since such stents are very well known in the art and self-expansion reduces the number of mechanical actions that are needed to deploy the stent. When the stent is self-expandable, it can be used with the wire taught by Bashiri et al. (see figure 15; column 9 lines 25-40). The push wire (194) is used to position the stent within the desired surgical site. After proper positioning, the stent is released from the push wire when the severable junction (196) is electrolytically detached. It would have been obvious to one skilled in the art to modify Callol to make the stent self-expandable so that it can be connected to a single push wire from which it is easily released as taught by Bashiri et al. in

order to minimize mechanical actions needed to deploy the stent as well as being able to temporarily implant the stent for an extended period of time. The wire is thermally and electrically conductive.

Regarding claims 14 and 15, it would have been obvious to one skilled in the art to construct the electrolytic detachment site to remain attached until the stent is fully deployed. Since the push wire is used to properly position the stent, it would have been obvious to keep this connection present until the stent has reached its fully deployed position. An earlier detachment might result in displacement of the stent since its configuration continues to change slightly until it is fully deployed.

Regarding claims 34-36, Bashiri et al. teaches forming part of the severable junctions out of radiopaque material since it is desirable to be able to visualize where the end of the implantable device is located (column 6, lines 44-50). Regarding claim 37, Bashiri et al. does not expressly teach a plurality of radiopaque markers but it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (*St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callol in view of Globerman and Bashiri et al. as applied to claims 8 and 11 above, and further in view of Camrud et al. (US 6,699,280). Callol in view of Globerman and Bashiri et al. discloses the invention substantially including a severable junction between the push wire and the stent but fails to disclose that the severable joint is bioabsorbable.

However, Camrud et al. teaches that a severable junction between two portions of an implantable medical device can be formed by a bioabsorbable connection. The bioabsorbable connection degrades upon interaction with fluids within the body lumen to a point at which the two portions break apart (col. 10, ll. 13-20). It would have been obvious to one skilled in the art

to further modify Callol to substitute a bioabsorbable connection as taught by Camrud et al. with the electrolytic detachment site taught by Bashiri et al. since such a modification would have been a simple substitution of known methods of forming a severable junction between two portions of a medical device.

Claims 16-19, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol in view of Globerman and Bashiri et al. as applied to claim 15 above, and further in view of Ravenscroft (US 5,702,418). It is noted that a typographical error appearing in the final office action mailed 1/29/2009, misidentifying Globerman as "McGuinness" in this rejection, has been herein corrected. Callol in view of Globerman and Bashiri et al. discloses the invention substantially but fails to disclose that the device is configurable from the initially deployed configuration to the predeployed configuration.

However, Ravencroft teaches using a catheter to keep a self-expanding stent in a collapsed configuration until deployment. Ravencroft further teaches that it is advantageous to have a delivery device that allows partial deployment and retraction of the stent through an attachment at the proximal end of the stent so that the surgeon can recover a stent that is not properly positioned during deployment. It would have been obvious to one skilled in the art to house the stent with a pull wire connected to its proximal end as taught by Bashiri et al. in a catheter as taught by Ravencroft so that the stent may be partially deployed and then returned back to the predeployed position in order to gain the advantage of being able to recover an incorrectly positioned stent.

Regarding claims 18 and 19, the stent cannot be fully deployed at least until the entire stent is free from the catheter. As seen in fig. 15 of Bashiri et al., the very distal end of the push wire is distal of the proximal-most portion of the stent and therefore a portion of the push wire and the stent are free of the lumen before the stent reaches its fully deployed position.

Regarding claims 44 and 45, it is old and well known to include radiopaque markers on catheters particularly at their distal ends and is further taught by Bashiri et al. (catheter 102; markers 106). Such a modification would have been obvious to one skilled in the art in order to monitor the position of the catheter within a patient's vasculature.

(10) Response to Argument

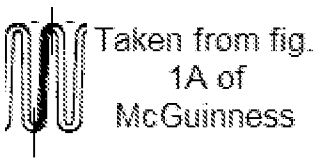
Regarding the rejections of claims 1, 20-24, 26-30, and 33 under 35 USC 103 over Callol in view of Globerman and claims 1, 3, 20, 23, 24, 26-28, 30, 33, and 40 under 35 USC 103 over McGuinness in view of Globerman, Appellant argues that Callol in view of Globerman and McGuinness in view of Globerman each fails to disclose interconnected stent members consisting of first stent members and second stent member, wherein the second stent members are oriented in a substantially longitudinal direction in the unexpanded state and in a substantially circumferential direction in the expanded state.

In particular, Appellant argues that the second stent members of Callol (14 in figures 1-3) and McGuinness (32 in figure 1A) are not substantially longitudinal in the unexpanded state because they include a curved portion (for example, 34 in figure 1A of McGuinness) bridging two longitudinally oriented portions. Appellant argues that the curved portions must be considered part of the claimed plurality of interconnected stent members. Because of the transitional phrase "consisting of" in line 6 of claim 1, Appellant argues that the presence of these curved portions in Callol and McGuinness distinguishes the claimed invention from the prior art.

However, the curved portions which bridge together two longitudinally extending second stent members on either Callol or McGuinness can be considered an additional element and not one of the claimed interconnected stent members. In other words, although the plurality of

interconnected stent members consist only of the claimed first and second stent members, the transitional phrase “comprising” in line 3 of the claim allows additional elements to be present in the stent assembly such as a bridge connecting the claimed second stent members. Appellant argues that it is inappropriate to considered portions of the ring (14) of Callol the claimed stent members, while considering other portions of the ring to be elements other than the claimed stent members. However, it is noted that the entire stent of the instant application is interconnected, including the claimed backbone, and yet, the instant application does not considered the backbone to be one of the interconnected stent members. The examiner maintains that the curved portions of ring (14) of Callol may be considered bridges, for example, that form the connection between the claimed interconnected stent members.

Alternatively, even if the entire rings (14) of Callol or McGuinness (32, 34) are considered the second stent members, so that each second stent member comprises a straight portion and half of an adjacent connected curved portion in the stents of either Callol or McGuinness, the second stent member can be considered substantially longitudinally directed in the unexpanded configuration, especially compared to its expanded circumferential orientation as taught by Globerman, since a large portion of the second member is longitudinally directed. The figure appearing below illustrates what the examiner has considered a second stent element of McGuinness when the entire rings (32 and 34) are considered a plurality of second stent members. Lines have been added by the examiner to show the boundaries of a single second stent member and the member has been shaded in. This can be similarly applied to the device of Callol.



It is noted that the examiner has used the teachings of Globerman, which discloses that it is well known in the art to fully expand a similarly wavy ring so that portions of the ring that are longitudinally directed when a stent is in its unexpanded state become circumferentially directed in the stent's expanded configuration (figures 14, 15), to gain the obvious advantage of a greater radial expansion ratio. No substitution of the rings of Globerman for the rings of Callol or McGuinness has been suggested. Rather, it would have been obvious in view of Globerman to fully expand the rings already disclosed by Callol or McGuinness. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The remaining claims are rejected in further view of Bashiri (claims 8-11, 13-15, and 34-37), Camrud (claim 12), and Ravenscroft (claims 16-19, 44, and 45), and are argued only in so far as these references fail to remedy Appellant's asserted deficiencies discussed above with respect to Callol in view of Globerman, and McGuinness in view of Globerman.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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